UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/273,957	03/22/99	WANG H	GC477C1

HM12/0404

GENENCOR INTERNATIONAL
925 PAGE MILL ROAD
PALO ALTO CA 94304

EXAMINER	
WALICKA, M	
ART UNIT	**PAPER NUMBER**
1652	11

DATE MAILED: 04/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/273,957	WANG ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06/02/01 and 05/03/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *18-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 56-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152) .
20)☒ Other: *US Patent No. 6,072,015* .

The examiner acknowledges the preliminary amendment filed on March 5, 2001. The amendments were entered as requested.

Applicants' election, without traverse, of Group I, claims 1-17 and 56-58, drawn to phenol oxidizing enzyme is acknowledged. Claims 18-55 are withdrawn from consideration as drawn to the non-elected subject matter.

Detailed Office Action

1. Objections

1.1. Drawings

This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

1.2. Claims

Claim 2 is objected to for failing to further limit claim 1. Claim 2 is drawn to the phenol oxidizing enzyme of claim 1 capable of modifying the color associated with a dye or colored compound. The claim does not further limit claim 1 because every oxidizing enzyme changes the color of dye.

2. Rejections

2.1. 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-14, and 56-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to all purified phenol oxidizing enzymes, obtainable from the genus *Stachybotrys.* The term phenol oxidizing defines a generic function including the following enzymatic activities: oxidases [e.g. laccases (EC 1.10. 3. 2), catechol oxidases (EC 1.10. 3. 1) and bilirubin oxidases (EC 1. 3. 3. 5)] and peroxidases (EC 1. 11. 1. 7). In addition to the native enzymes, the term "obtainable" refers to any phenol oxidizing enzyme that might be produced in *Stachybotrys* after transforming it with the the

appropriate encoding gene. The *Stachybotrys* genus includes *S. parvispora, S. chartarum, S. kampelensis, S. theobromae, S. bisbyi, S. cylindrospora, S. dichroa, S. oenanthes and S. nilagerica.* The specification, however, only provides a single representative species of said enzyme that is a phenol oxidizing enzyme natural to *Stachybotrys* MUCL 38898, having the amino acid sequence of SEQ ID NO:2. The specification fails to describe additional representative species of the phenol oxidizing enzyme by any identifying structural characteristics or properties other than activity of oxidation of aromatic OH group, for which properties no predictability of structure is apparent. Given the lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 2-14 and 56-58 are included in the rejection because they depend on the rejected claim 1 and do not cure its deficiencies.

Claims 1-14, 15, 17, and 56-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for phenol oxidizing enzyme natural to *Stachybotrys chartarum*, MUCL 38898, having the sequence defined by SEQ ID NO:2, does not reasonably provide enablement for any phenol oxidizing enzyme having any substrat specificity that might be obtainable from any species of the genus *Stachybotrys.* Also, the specification does not provide any insertion, deletion, substitution, and combination thereof, mutants of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broader than the enablement provided by the disclosure with regard to the huge number of all possible phenol oxidizing enzymes that might be obtained from the genus *Stachybotrys*, which include oxidases, catechol oxidases, bilirubin oxidases and peroxidases. The species of *Stachybotrys* include S. *parvispora, S. chartarum, S. kampelensis, S. theobromae, S. bisbyi, S. cylindrospora, S. dichroa, S. oenanthes and S. nilagerica.* Also, one may obtain a phenol oxidizing enzyme from any organism whose gene was introduced to organism belonging to genus *Stachybotrys.* Thus, obtaining the claimed phenol oxidizing enzyme requires undue experimentation. Factors to be considered in determining whether undue experimentation is required, are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompasses any phenol oxidizing enzyme, having any substrate specificity, from *Stachybotrys* or any biological source, the gene of which is to be expressed in genus *Stachybotrys*. Also, claims 15, 17, and 57 are drawn to insertion, deletion, substitution and combination thereof mutants. While methods of protein isolation are well known in the relevant art and skills

of the artisans are highly developed, search for a phenol oxidizing enzyme prompts screening vast number of species for required activity.

In addition, obtaining any phenol oxidizing enzyme from any species of the genus *Stachybotrys* requires also transforming these species with phenol oxidizing enzyme genes from other organisms. While molecular genetic manipulations necessary to obtain transformants containing genes coding for many proteins are known in the prior art and the skills of artisans are highly developed, phenol oxidizing genes from all organisms are not cloned, and cloning all such genes would be well outside the realm of routine experimentation.

The working examples provide the guidance only for measuring phenol oxidizing activity and cloning the gene of the phenol oxidizing enzyme of SEQ ID NO:2 from *Stachybotrys chartarum*, MUCL 38898. Specification discloses transformation with this gene only in case of *Aspergillus niger, Trichoderma reesei and Saccharomyces cerevisiae* and is silent about transformation of any organism belonging to *Stachybotrys.* Thus, the examiner finds that one skilled in the art would require additional guidance such as defining the species of the phenol oxidizing enzyme and its substrate, its amino acid sequence and *Stachybotrys* species to be used. Without such guidance, the experimentation left to those skilled in the art is undue.

2.2. 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 4, 5, 13, 14 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolle et al (US Patent 6,072, 025).

Claim 1, 2, 4, 5, 13, 14 and 56 are directed to a purified phenol oxidizing enzyme from *Stachybotrys*. A phenol oxidizing enzyme from *Stachybotrys*, the laccase form *Stachybotrys chartarum*, is thaught by Bolle at al in a method for paint preparation from lignin, column 6, line 1 of the patent, for producing a painted article (claim 1 of the patent).

Claim 2 of the instant invention limits claim 1 to the phenol oxidizing enzyme from *Stachybotrys* that is capable of modifying the color associated with a dye or colored compound. In the patent, the laccase from *Stachybotrys chartarum* was used for the very same purpose, see column 6, line 1 of the patent.

Claim 4 and 5 limit genus *Stachybotrys* to species, among others, *S. chartarum*. Bolle et all used as the source of their phenol oxidizing enzyme *S. chartarum*, see column 4, line 60 of the patent.

Claim 13 and 14 limit phenol oxidizing enzyme of claim 1 by defining its optimum of pH. It is 6-9 at 20° C, as measured for reaction with two substrates. The pH requirement of enzyme used by Bolle is within the same range as pH of the claim invention, because Bolle et al used the range of pH 6.5-8 for temperatures 15° C to 40° C, column 4 line 60.

2.3. Nonstatutory double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 17 and 56-57 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 2, 3, of copending Application No. 09/218,702 (**702**) filled on December 12, 1298. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

> Claim **1 of 702** is drawn to a phenol oxidizing enzyme obtainable form *Stachybotrys* and having at least 80% identity to the phenol oxidizing enzyme having the amino acid sequence as disclosed in SEQ ID NO:2.

Claim **2 of 702** reads: "The phenol oxidizing enzyme of Claim 1 wherein the *Stachybotrys* includes *S. parvispora, S. chartarum, S. kampelensis, S. theobromae, S. bisbyi, S. cylindrospora, S. dichroa, S. oenanthes and S. nilagerica.*"

Claim **3 of 702** reads: "The phenol oxidizing enzyme of Claim 1 having the amino acid sequence as disclosed in SEQ ID NO:2."

SEQ ID NO:2 of 702 is identical to SEQ ID NO:2 in the instant application. The sequence identifies protein obtained from *Stachybotrys chartarum* having accession number MUCL 38898.

a) Claims 1 and 56 of the instant application are drawn to a purified phenol oxidizing enzyme obtainable form *Stachybotrys*. These claims have a broader scope than claims **1 and 3 of 702** that recities a phenol oxidizing enzyme obtainable from *Stachybotrys* and having at least 80% identity to the phenol oxidizing enzyme having the amino acid sequence as disclosed in SEQ ID NO:2.

b) Claim 3, 10, 11, 12, 13 and 14, of the instant application teach features of the enzyme that are determined by the amino acid sequence identified by SEQ ID NO:2. Therefore, these claims and claim **1 of 702** are not patentably distinct.

c) Claim 4 of the instant application encompass the phenol oxidizing enzyme that is at least 80% identical to SEQ ID NO:2 that may be obtained from the same set of *Stachybotrys* species as recited in claim **2 of 702.** Claim 4 of the instant application and claim **2 of 702** are, therefore, not patentably distinct.

d) Claims 5, 6, 7, 8, 9, of the instant application have smaller scope than claim **1 and 2 of 702** but are not patentably distinct.

e) Claims 15, 17 and 57 have broader scope than claim **1, 2 and 3 of 702**, but are not patentably distinct.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the copending application 09/218702. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

2.4. Statutory double patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 15 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of copending Application No. 09/218702. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600